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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/692,634	10/19/2000	Paul John Rennie	8308	8314

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EXAMINER	
SHARAREH, SHAHNAM J	

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 06/27/2002 9

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/692,634	Applicant(s) RENNIE ET AL.	
	Examiner Shahnam Sharareh	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10/19/2000, 4/26/02* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9 and 20-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9 and 20-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5 .
4) ☒ Interview Summary (PTO-413) Paper No(s). 6 .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. Applicant's elections of claims 1-9, 20-30 in Paper No. 8/A is acknowledged. Claims 10-19, 31-53 have been canceled. Claims 1-9, 20-30 are pending and are under consideration.

Priority

Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

> The second application (which is called a continuing application) must be an application for a patent for an invention which is also disclosed in the first application (the parent or provisional application); the disclosure of the invention in the parent application and in the continuing application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *In re Ahlbrecht*, 168 USPQ 293 (CCPA 1971).

2. In the instant case, the parent applications fail to nasal compositions for treatment of cold comprising pyroglutamic acid, and a metal salt, and methods of preventing or treating cold using such compositions

Thus, the effective priority date used for the examination of the instant application is October 19, 2000.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-9, 20-30 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "low" in claim 1 is a relative term which renders the claim indefinite. The term "low" is not defined by the claim, the specification does not provide a standard

for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Claim 7 recites the limitation "the mucoadhesive agent" in line 1. There is insufficient antecedent basis for this limitation in the claim. The claim appears to be depending from claim 6.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1-9, 20-30 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 1-9, 20-30 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating cold, does not reasonably provide enablement for prevention cold. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The state of the prior art concerning methods of preventing a disease condition requires adequate assessment of patient disposition, identification, screening, and monitoring the clinical outcome in given time intervals. There is no correlation between the working example describing an in the instant specification and method of preventing pathological conditions such as cold and influenza viruses. The amount of guidance

presented in the specification fails to present a required amount of guidance to perform the claimed method without undue experimentation. Nor is guidance provided as to a specific protocol to be utilized in order to prove the efficacy of the presently claimed compounds in preventing said conditions. The burden of enabling the prevention of a disease (ie. the need for additional testing) would be greater than that of enabling a treatment due to the need to screen those humans susceptible to such diseases and the difficulty to prove that the administration of the drug was the sole reason that prevented the condition. Accordingly, undue experimentation is necessary to practice the invention commensurate in scope with the claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-5, 20-27 rejected under 35 U.S.C. 102(b) as being anticipated by Gangadharan et al US Patent 5,643,582.

Gangadharan discloses suitable moisturizes comprising a humectants such as 2-pyrrolidinone-5-carboxylic acid (same as instant pyroglutamic acid), a moisturizing agent, a polymeric bioadhesive agent, ascorbyl palmitate, benzoic acid, and a pH modifier a carboxylic acid, a metal salt of malic acid, a therapeutic agent and a pH modifying agent (see abstract, col 2, lines 50-67; col 4, lines 5-65; col 5, lines 20-30, 33-66; col 6, lines 6-56; col 7, lines 30-33; col 10, line 50; col 13-14). Gangadharan states

that his compositions can be administered nasally (col 10, line 49). Thus, Gangadharan anticipates the limitations of the instant claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 1-9, 20-30 are rejected under 35 U.S.C. 103(a) as being unpatentable

over Davidson et al US Patent 6,080,783 in view of Szentmiklosi et al US Patent 5,244,880 and Gangadharan et al US Patent 5,643,582.

The instant claims are directed to nasal compositions comprising an effective amount of pyroglutamic acid, an effective amount of metal salts, a suitable carrier.

Davidson teaches viscous nasal gel delivery system comprising zinc metal, a thickener, and other suitable carrier ingredients for treatment of cold. (see abstract, examples 1-6). Davidson's compositions do not contain pyrolgutamic acid.

Szentimiklosi discloses L-pyroglutamic acid or salts thereof in therapeutic topical preparations (see abstract, example 9). Szentimiklosi's compositions contain suitable topical ingredients such as an organic acid, a mucoadhesive agent and even a propellant (examples 2-9). Szentimiklosi does not teach nasal formulations of his compositions.

Gangadharan discloses suitable moisturizes comprising a humectants such as 2-pyrrolidinone-5-carboxylic acid (same as instant pyroglutamic acid), a moisturizing agent, a polymeric bioadhesive agent, ascorbyl palmitate, benzoic acid, and a pH modifier a carboxylic acid, a therapeutic agent and a pH modifying agent (see abstract, col 2, lines 50-67; col 4, lines 5-65; col 5, lines 20-30, 33-60; col 6, lines 6-56; col 10, line 50; col 13-14).

Davidson, Szentimiklosi, and Gangadharan and teach topical compositions, thus, their teachings are viewed as being in the same field of endeavor.

It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be

used for the very same purpose (see MPEP 2144.06); therefore, one ordinary skilled in the art would have had a reasonable expectation to succeed in formulating a nasal composition for treatment of cold by mixing the zinc containing nasal compositions of Davidson with pyroglutamic acid containing compositions of Szentimklosi or Gangadharan and then adjusting the pH to a desired range using suitable carrier systems for nasal delivery. Furthermore, absence of showing a criticality, optimizing viscosity and pH values of a topical composition would not impart patentability, because such modifications can be obtained by routine experimentations.

7. Claims 1-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Elliott et al US Patent 5,905,062 in view of Gangadharan et al US Patent 5,643,582.

Elliott et al disclose a liquid composition comprising a suitable anionic, nonionic or amphoteric surfactant, a suitable carrier selected from a group with multiple hydroxyl groups, comprising 2 to about 6 hydroxyl groups (see abstract, col 7 lines 13-26.) Elliott's composition comprise various moisturizers such as L-proline (pyroglutamic acid) in ranges of 0.5% to about 20% which falls within the instant disclosed ranges of pyroglutamic acid, therefore, Elliott□s composition comprise of safe and effective amount of L-proline (see col 12 lines 51-68, claim 19). Elliott□s composition also comprises a suitable metal salt (see claim 12 line 33). Finally, Elliott□s compositions preferably have a pH of 4-10 (see col 13 lines 51-53). Elliott does not teach nasal that contains a metal salt compositions.

The teachings of Gangadharan have been discussed previously. They are primarily used to show that modifying topical compositions into nasal compositions is conventional and well within purview of one of ordinary skill in the art.

Accordingly, even though Elliott does not explicitly teach a nasal containing a metal salt, it would have been obvious to one of ordinary skill in the art at the time of invention to add a zinc gluconate to Elliott's composition and further prepare a nasal formulation from Elliott's composition, because as shown by Gangadharan, the ordinary skill in the art would have had a reasonable expectation of success in providing moisturizing effects nasally to exert their therapeutic effects on epithelial cells.

Conclusion

No claims are allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shahnam Sharareh whose telephone number is 703-306-5400. The examiner can normally be reached on 8:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie can be reached on 703-308-4612. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1123.

ss
June 24, 2002

RUSSELL TRAVERS
PRIMARY EXAMINER
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